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EXAMINER	
PALLAY, MICHAEL B	

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1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,470	JAIN ET AL.	
	Examiner	Art Unit	
	MICHAEL B. PALLAY	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-50,54-106,110 and 111* is/are pending in the application.

4a) Of the above claim(s) *54-86,110 and 111* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *27-50 and 87-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/03/2010; 01/27/2011; 04/11/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of applicant's response dated January 27, 2011. Claims 27 and 56 have been amended. Claims 27-50, 54-106, 110, and 111 are pending in the application, with claims 54-86, 110, and 111 withdrawn from consideration as being drawn to non-elected inventions. Thus, claims 27-50 and 87-106 are under current examination.

The claim rejections indicated in the previous Office action dated July 27, 2010, are hereby withdrawn in light of the declaration filed on January 27, 2011, under 37 CFR 1.131 to overcome the Straub et al. reference (U.S. Patent No. 6,395,300; issued May 28, 2002).

New rejections are made in the present Office action which constitute the complete set of rejections and objections being applied to the instant application.

Change of Examiner

The examiner and Art Unit assigned to the instant application have changed. The new examiner is Michael Pallay in Art Unit 1617. Contact information is provided at the end of this Office action.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set

forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 27, 2011, has been entered.

Information Disclosure Statement

The information disclosure statement filed November 3, 2010, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. Specifically, such copies of WO 01/92584 A1 and EP 0 602 702 A1 have not been provided. The statement has been placed in the application file, but the information referred to therein has not been fully considered.

The information disclosure statement filed November 3, 2010, also fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Specifically, such concise explanation of “Notice of Decision to Grant dated 8/30/2010 cited in related Japanese Patent Application No. 2003-565446” has not been provided. It has been placed in the application file, but the information referred to therein has not been fully considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-47, 50, and 87-106 are rejected under 35 U.S.C. 102(b) as being anticipated by Eickhoff et al. (U.S. Patent No. 5,518,738; issued May 21, 1996; of record).

Claims 27-47, 50, and 87-106 encompass an oral solid dose rapidly disintegrating nanoparticulate active agent formulation comprising: (a) a solid dose porous matrix comprising at least one pharmaceutically acceptable water-soluble or water-dispersible excipient, and (b) within the solid dose porous matrix a nanoparticulate active agent composition comprising: (i) a poorly soluble active agent having an effective average particle size of less than about 2000 nm prior to inclusion in the dosage form; and (ii) at least one surface stabilizer adsorbed on the surface thereof; wherein the active agent is selected from the group consisting of analgesics, anti-inflammatory agents, anthelmintics, anti-arrhythmic agents, antibiotics, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, antihistamines, antihypertensive agents, antimuscarinic agents, antimycobacterial agents, antineoplastic agents, immunosuppressants, antithyroid agents, antiviral agents, anxiolytic sedatives, astringents, beta-adrenoceptor blocking agents, blood products and substitutes, cardiac inotropic agents, contrast media, corticosteroids, cough suppressants, diagnostic

agents, diagnostic imaging agents, diuretics, dopaminergics, haemostatics, immunological agents, lipid regulating agents, muscle relaxants, parasympathomimetics, parathyroid calcitonin and biphosphonates, prostaglandins, radio- pharmaceuticals, sex hormones, anti-allergic agents, stimulants and anoretics, sympathomimetics, thyroid agents, vasodilators, and xanthines; and wherein the solid dose porous matrix surrounding the nanoparticulate active agent and at least one surface stabilizer disintegrates or dissolves upon contact with saliva in less than about 3 minutes.

Eickhoff et al. teaches a rapidly-acting ("more rapid onset of action") solid oral dose form pharmaceutical composition comprising "poorly soluble" active drugs in nanoparticulate form, for example anti-inflammatory agent such as NSAIDs in crystalline phase and nanoparticulate, dispersed in mixtures of hygroscopic sugar (i.e., sucrose, dextrose, mannose, lactose, mannitol), polyvinylpyrrolidone and sodium lauryl sulfate, wherein the polyvinylpyrrolidone surface modifier is adsorbed on the surface of the active drug (abstract; column 2, lines 41-50; column line 59 through column 3, line 32; column 3, lines 36-48; column 5, lines 45-52; examples; claims 1-10 and 15; claims 1-10), wherein the average particle size of the active is less than about 1000 nm, preferably less than 300 nm, with an example of 200 nm (column 3, lines 49-59; example 1); the concentration of the active is in range from about 0.1 to 60% (column 4, lines 16-21); the concentration of polyvinylpyrrolidone is in the range from about 0.1 to about 90% (column 4, lines 21-24 and column 5, lines 42-44); the concentration of the hygroscopic sugar (i.e., mannitol) is in the range of from 10 to 75% (column 5, lines 53-

54); and the concentration of the sodium lauryl sulfate is in the range of from 0.1 to 10% (column 5, lines 55-57); and the dispersion is spray dried to a fine powder in a fluidized bed coater or the final composition is prepared in caplets (Examples). Eickhoff et al. also discloses a method of treating a mammal comprising administering said composition (claims 11-14).

Although Eickhoff et al. discloses NSAIDs as the class of drugs in said oral dose form, for example an oral solid dosage form comprising nanoparticulate naproxen (approximately 200 nm) having mixtures of polyvinylpyrrolidone, mannitol and sodium lauryl sulfate dispersant adsorbed on the surface (Examples 1 and 2), Eickhoff et al. expressly teaches that other active drugs such as antibiotics can be utilized in place of NSAIDs (column 2, lines 49- 51).

With respect to a “porous matrix”, such property or characteristic is inherent to the referenced mixtures of water-soluble or water-dispersible excipients, namely hygroscopic sugar (i.e., sucrose, dextrose, mannose, lactose, mannitol), polyvinylpyrrolidone and sodium lauryl sulfate, into which the nanoparticulate is dispersed. According to the declaration of Stephen Ruddy filed January 27, 2011, the claimed invention was reduced to practice by adding the nanoparticulates with surface stabilizers to such water-soluble or water-dispersible excipients (mannitol), spray drying the mixture, adding further excipients, and compressing into tablets (paragraphs 4-7). Thus, the “porous matrix” is mannitol. Eickhoff et al. teaches mannitol, and thus Eickhoff et al. anticipates the instant invention.

With respect to "the solid dose porous matrix surrounding the nanoparticulate active agent and at least one surface stabilizer disintegrates or dissolves upon contact with saliva is less than about 3 minutes", such property or characteristic is inherent to the referenced "more rapid onset of action" composition since the essential components of Eickhoff et al. are identical to the instant composition (that is an oral solid dose nanoparticulate having an average particle size of less than 1000 nm, surface stabilizer adsorbed on the surface thereof such as polyvinylpyrrolidone, dispersed in a water-soluble or water-dispersible excipient (e.g., mannitol and sodium lauryl sulfate)). Thus, Eickhoff et al. anticipates the instant invention.

With respect to the specific average particle sizes, the referenced average particle size of the active, e.g., less than about 1000 nm, preferably less than 300 nm, more preferably 200 nm, lies within the instantly claimed particle size and thus anticipates the claimed invention.

With respect to the specific amounts of active agent or excipient in said composition, the referenced concentration of the active agent which is in range from about 0.1 to 60% and the referenced concentration of polyvinylpyrrolidone which is in range from about 0.1 to about 90%, lies within the instantly required amounts of active and/or excipients and thus anticipates the claimed invention.

With respect to "said excipient is selected from the group consisting of a direct compression material and a non-direct compression material", such property or characteristic is inherent to the referenced excipients such as spray-dried mannitol, as

evidenced by the instant specification at page 20. Thus, Eickhoff et al. anticipates the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-50 and 87-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eickhoff et al. in view of applicant's admitted prior art of record (pages 1, line 31 through page 4, line 22) or Acosta-Cuello et al. (WO 97/18796 A1; published May 29, 1997; of record).

The teaching of Eickhoff et al. has been discussed in the above 35 USC 102(b) rejection. Applicant's admitted prior art of record and WO '796 are provided as supplemental references to demonstrate the routine knowledge in preparing micro- or nano-particulate compositions in a rapidly disintegrating or dissolving or fast-melting solid oral dose or matrix form (see particularly page 1, line 31 through page 4, line 22 of the instant specification; abstract, page 5, lines 19 through page 6, line 5 of WO '796). Alternatively, assuming arguendo that Eickhoff's formulation differs from the instant invention (i) mainly in the feature of “rapidly disintegrates upon contact with saliva in less than three minutes" recited in claim 87. However, such determination of appropriate dosage form having rapidly disintegrating dosage form upon contact with saliva in less than about 3 minutes for treatment involving each of the above mentioned formulations would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the known dosage formulation art.

As evidenced by the applicant's admitted prior art or WO '796, there are general references indicating that pharmaceuticals generally may be delivered in rapidly dissolving formulations, as well as disclosing benefits to be achieved by "rapidly dissolving formulation" or "fast melt" dosage forms versus other modes of administration. Therefore, there exist general art accepted motivations for formulating drugs for "rapidly dissolving formulation" or "fast melt" dosage forms.

With respect to the preparation of said composition via lyophilization, applicant's admitted prior art of record (particularly page 3, lines 13-22) teaches the routine

knowledge in preparing fast disintegrating oral dosage form or fast melt dosage formulation via freeze-drying techniques. The above references in combination make clear that the preparing of said rapidly disintegrating or dissolving dosage formulation or fast melt dosage forms made by various techniques including fluid bed granulation or lyophilization is well known and within the skill of an artisan. Thus, one would have been motivated to combine these references and make the modification because they are drawn to the same technical fields (constituted with same ingredients and share common utilities), and pertinent to the problem with which applicant is concerned about. MPEP 2141.01(a).

Claims 27-50 and 87-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eickhoff et al. in view of applicant's admitted prior art of record (pages 1, line 31 through page 4, line 22) or Acosta-Cuello et al., and further in view of Kerkhof et al. (WO 01/45674 A1; of record).

See above 35 USC 103 (a) rejection.

Similar to Eickhoff et al., Kerkhof et al. discloses nanoparticle compositions comprising a nonsoluble drug including analgesics, anti-inflammatory agents including NSAIDs such as indomethancin, naproxen and ketoprofen, antibiotics, anthelmintics, anti-arrhythmic agents, anticoagulants, antidepressants, antidiabetic agents, antiepileptics, etc.., in water-dispersible excipient (i.e. mannitol, lactose, carbonates, bicarbonates, etc...), and/or surface stabilizer such as surfactant (i.e., polyvinylpyrrolidone, sodium dodecylsulfate (commonly known as sodium lauryl sulfate),

carboxymethylcellulose, etc...), wherein said composition is made by fluid bed granulation and spray-drying method where a suitable excipient, such as spray-dried lactose, is fluidized by an upward gas stream; and wherein one part by weight of an active ingredient is combined with about 2.5 to about 50 parts, preferably about 2.5 to about 20 parts of an excipient (abstract; page 10, lines 1-12; page 10, line 25 through page 11, line 9; page 11, lines 10-27; page 15, lines 1-18; page 8, lines 11-16 and 25-27; page 15, lines 1-17; page 12, line 29 thru page 13, line 6; Claims, particularly claims 1-2, 7, and 19). According to Kerkhof et al., the nanoparticle can have a mean particle size between 50-1000 nm (Claim 2 and page 7, lines 20-23). The composition can be fashioned into tablets, capsules or syrups (page 14, lines, 12-15). According to Kerkhof et al., the method of preparing a nanoparticle composition can comprise spraying a solution of a poorly soluble drug and a solvent into a bed of carrier particles (claim 1). The solution may further comprise a surface modifier, such as a surfactant (claims 1, 18, 19). The nanoparticle composition can have a mean particle size of around between 50-1000nm (claim 2 and page 7, lines 20-23). Kerkhof et al. also discloses a method of administering a nanoparticle composition comprising a surface modifier, such as a surfactant, and a drug to a human (page 14, lines 16- 27). Prior to administration, the composition may be formulated into a tablet (page 14, lines 12- 15).

The modified teaching of Eickhoff et al. (combination of Eickhoff et al. and the applicant's admitted prior art of record or WO '796) includes all that is recited in the claimed invention except the specific particle size or the active agent, namely "less than about 100 nm", more particularly "less than about 50 nm" recited in claims 94 and 95

respectively. To incorporate such teaching into the modified teaching of Eickhoff et al., would have been obvious in view of Kerkhof et al. which teaches the routine knowledge in preparing nanometer particles of a non-soluble actives (e.g., antibiotics and anti-inflammatory agent including NSAIDs such as indomethancin, naproxen and ketoprofen) to a mean particle size between 50-1000 nm in carrier excipients and/or surface stabilizer and the use of effervescent such as bicarbonate in said composition.

The above references in combination make clear that the determination of the specific (nano) particle size of the poorly soluble active agent required in the instant invention and the use of bicarbonate in said composition as a secondary ingredient in areas of pharmaceutical dosage art are well known. Thus, one having ordinary skill in the art would have been motivated to combine the references and make such modification to extend the usage of said composition in rapidly disintegrating nanoparticulate form to accommodate patient's preference and needs where the compliance could be improved with an effective and well tolerated drug.

Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-50 and 87-106 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 and 21 of U.S. Patent No. 6,165,506 in view of applicant's admitted prior art of record (specification page 3, lines 13-22).

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the patent are directed to an

oral solid dose nanoparticulate formulation comprising water-soluble or water-dispersible excipient and a poorly soluble active agent less than about 2000 nm prior to inclusion in the dosage forms and at least one surface stabilizer.

Since the transitional term "comprising" is inclusive or open-ended and does not exclude additional, unrecited elements or method steps, the inclusion of alkali agent to increase the dissolution rate of nanoparticulate naproxen disclosed in US '506 falls within the scope of the invention and makes obvious the instant invention.

Although USP '506 is silent about the characteristic of said composition being "rapidly disintegrating" and having a “porous matrix”, such properties or characteristics are inherent to the referenced composition since the essential components of USP '506 are identical to the instant composition. Thus, USP '506 makes obvious the instant invention.

Claims 27-50 and 87-106 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-177 of U.S. Patent No. 7,276,249 in view of applicant’s admitted prior art of record (page 1, line 31 to page 4, line 22) or Kerkhof et al.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant invention overlaps with the patented claims.

Although independent claims of 1, 64, 121, 178 and 184 of US '249 do not specially recite the instant "at least one pharmaceutically acceptable water-soluble or

water-dispersible excipient", it is clear from reading the referenced claims 42-50, 56, 99-103, 105-113, 118, 156- 160, 162-170 and 175 that said composition is prepared in the water soluble or dispersible excipients. Thus, US '249 makes obvious the instant invention.

With respect to the instantly required rapidly disintegrating or dissolving property of said composition in claim 87, such determination of suitable dosage delivery form is considered an obvious task for the skilled artisan especially in view of the referenced claims 34, 97 and 154. Thus, USP '249 makes obvious the instant invention.

With respect to the instantly required specific nanoparticle sizes of the active drug and the specific amounts of active and inactive ingredients in claims 91-101, such optimization of known active and/or inactive ingredients is considered obvious task for the skilled artisan especially in view of the referenced claims 11-24, 26-29, 74-92, 114-115 and 131-149. Thus, USP '249 makes obvious the instant invention.

With respect to the preparation of said composition via "spray-dried mannitol and spray- dried lactose", "fluid bed granulation" or "lyophilized" or the preparation of said composition with "a direct compression material and a non-direct compression material", namely mannitol or lactose and effervescent agent, such determination of suitable technique to make "fast melt" or “rapidly disintegrating or dissolving" drug or using known secondary ingredients is considered an obvious task for the skilled artisan especially in view of the referenced claims 34-35, 97-98 and 154-155 and applicant's admitted prior art of record (pages 1, line 31 through page 4, line 22) or Kerkhof et al. Thus, USP '249 makes obvious the instant invention.

With respect to the preparation of a "porous matrix", such determination of appropriate porous matrix having rapidly disintegrating dosage form upon contact with saliva in less than about 3 minutes for treatment involving each of the above mentioned formulations would have been routinely made by those of ordinary skill in the art and is within the ability of tasks routinely performed by them without undue experimentation, especially in light of the known dosage formulation art (for example, Kerkhof et al. and applicant's admitted prior art).

As evidenced by the applicant's admitted prior art and Kerkhof et al., there are general references indicating that pharmaceuticals generally may be formulated and delivered by porous matrix rapidly dissolving formulations, as well as disclosing benefits to be achieved by "rapidly dissolving formulation" or "fast melt" dosage forms versus other modes of administration. Therefore, there exist general art accepted motivations for formulating drugs for porous matrix "rapidly dissolving formulation" or "fast melt" dosage forms.

It is further noted that applicant has numerous issued patents and pending applications encompassing the same or similar subject matter of the instant application. Applicant should review all subject matter considered the same or similar, and submit the appropriate Terminal Disclaimer(s). For example, 09/337675, 11/275069, 10/392303, 12/068706, etc., are drawn to same or similar subject matter(s).

Response to Arguments

The declaration filed on January 27, 2011, under 37 CFR 1.131 is sufficient to overcome the Straub et al. reference. Applicant's arguments regarding the rejections relying on Straub et al. are therefore moot.

Regarding applicant's argument that "rapid onset" and "rapid disintegration" are not equivalent (response page 16), such is not persuasive because, as noted in the above rejections, the claimed compositions and the composition of Eickhoff et al. is identical and therefore necessarily has the characteristic or property of "rapidly disintegrating."

Applicant's argument that neither the prior art cited in applicant's specification nor Acosta-Cuello et al. teach rapidly disintegrating nanoparticulate active agent compositions (response pages 17-18) is also not persuasive because Eickhoff et al. teaches such a composition given that "rapid disintegration" is an inherent property of the composition as noted above.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL B. PALLAY whose telephone number is (571)270-3473. The examiner can normally be reached on Monday through Friday, 8:30 AM to 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MBP

/GINA C. YU/
Primary Examiner, Art Unit 1617